

January 27, 2006

Dear Healthcare Provider:

Novartis is fully committed to assuring timely dissemination of safety information about their products to the healthcare community. We are writing to inform you of changes made to the Elidel<sup>®</sup> (pimecrolimus) Cream 1% package insert, including revision of the wording in the INDICATIONS AND USAGE section and addition of a WARNINGS sections that includes a BOXED WARNING. We inform you that there will also be a Medication Guide for patients.

In the U.S. Package Insert for Elidel Cream, the **INDICATIONS AND USAGE** Section now reads as follows:

Elidel<sup>®</sup> (pimecrolimus) Cream 1% is indicated as *second-line therapy* for the short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised adults and children 2 years of age and older, who have failed to respond adequately to other topical prescription treatments, or when those treatments are not advisable.

**Elidel Cream is not indicated for use in children less than 2 years of age (see WARNINGS, boxed WARNING, and PRECAUTIONS, Pediatric Use).**

The following **WARNINGS** Section, including a BOXED WARNING, has been added to the Elidel prescribing information:

#### **WARNING**

##### **Long-term Safety of Topical Calcineurin Inhibitors Has Not Been Established**

Although a causal relationship has not been established, rare cases of malignancy (e.g., skin and lymphoma) have been reported in patients treated with topical calcineurin inhibitors, including Elidel Cream.

Therefore:

- Continuous long-term use of topical calcineurin inhibitors, including Elidel Cream, in any age group should be avoided, and application limited to areas of involvement with atopic dermatitis.
- Elidel Cream is not indicated for use in children less than 2 years of age.

Prolonged systemic use of calcineurin inhibitors for sustained immunosuppression in animal studies and transplant patients following systemic administration has been associated with an increased risk of infections, lymphomas, and skin malignancies. These risks are associated with the intensity and duration of immunosuppression.

Based on this information and the mechanism of action, there is a concern about a potential risk with the use of topical calcineurin inhibitors, including Elidel Cream. While a causal relationship has not been established, rare cases of skin malignancy and lymphoma have been reported in patients treated with topical calcineurin inhibitors, including Elidel Cream. Therefore:


- Elidel Cream should not be used in immunocompromised adults and children.
- If signs and symptoms of atopic dermatitis do not improve within 6 weeks, patients should be re-examined by their healthcare provider and their diagnosis be confirmed (See PRECAUTIONS).
- The safety of Elidel Cream has not been established beyond one year of non-continuous use.

Healthcare professionals should report all serious adverse events suspected to be associated with the use of Elidel Cream to Novartis Pharmaceuticals Corporation, One Health Plaza, East Hanover NJ 07936 or by phone (888-NOW-NOVA or 888-669-6682) or the internet at <http://www.pharma.us.novartis.com>.

Alternatively this information may be reported to FDA's MedWatch Reporting System by phone at 1-800-FDA-1088, by facsimile 1-800-FDA-0178, by mail using the Form 3500 at <http://www.fda.gov/medwatch/index.html>.

Please see enclosed revised Package Insert and Medication Guide for complete prescribing information for Elidel Cream.

Sincerely,

*Alan L. Bess* 

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